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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,369	10/07/2005	Rikiichi Tagawa	TAGAWA1	1884

1444 7590 06/11/2008

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
06/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,369	TAGAWA ET AL.	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are pending in the application.

In response to the election restriction requirement dated 11/15/07, Applicants elected the nanopore size 10-20 nm with traverse. The traversal is on the basis that, first, the requirement appears to be predicated on an incorrect reading of the claims, since claims 5 and 7 are not different species from claim 3. Claim 3 recites the pore size of the membrane, and claims 5 and 7 recite the size of the pores of the prefilter. Applicant's arguments have been carefully considered and deemed persuasive, therefore the restriction requirement is withdrawn.

Claims 1-7 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Winge (US 6,399,357).

Winge teaches a process for preparing an albumin preparation which involves a step of filtration with a virus-removing membrane (e.g., claims 49, 54-56).

Therefore, the reference is deemed to anticipate the instant claim above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winge (US 6,399,357) in view of Chang (US 5,250,662).

Winge teaches a process for preparing an albumin preparation for therapeutic use (column 1, lines 35-67; column 2, lines1-10) which involves a step of filtration with a virus-removing membrane (e.g., claims 49, 54-56).

Winge does not teach doing a heat treatment in liquid state after the filtration with a virus-removing membrane or use of an anion exchanger before the filtration with a virus-removing membrane.

Chang teaches a purification method of albumin comprising heat-shocking the stabilized albumin solution for 2 hours at 60º C (e.g., column 18, lines 42-45) as in the limitation of claim 2: “heat treatment in a liquid state”. Chan et al. teach that albumin's main uses are as a plasma extender and for correction of hypoproteinemia. In addition, albumin is frequently used: (1) as stabilizing agent for other proteins contained in preparations administered for various treatments such as Factor VIII; (2) to maintain the colloid osmotic pressure; and (3) for in vivo transport functions, for example, of fatty acids and drugs (column 1, lines 38-44). Chan et al. also teach use of anion-exchange resin (as in the limitation of claims 4 and 6: “anion exchanger”) to remove contaminants

from an albumin-containing preparation (e.g., claim 1) for therapeutic uses (e.g., column 1, lines 38-44).

Neither reference expressly teaches the order of purification steps as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Winge by using a combination of steps including heat treatment or anion exchange filtration (column 18, lines 42-45; claim 1) as taught by Chang. The skilled artisan would have been motivated to do so in order to further purify the albumin. There would have been a reasonable expectation of success, given that both Winge and Chan et al. teach purification of albumin for therapeutic applications (column 1, lines 35-67; column 2, lines1-10 of Winge; column 1, lines 38-44 of Chang). The adjustment of particular conventional working conditions (e.g., determining appropriate purification steps and order of the steps within such method) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. As such, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g., determining types of purification steps including anionic exchange filtration, heat treatment and virus-filtration, and order thereof), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.". *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235

(CCPA 1955). See MPEP 2145.05). One would have been motivated to determine all optimum and operable conditions in order to achieve the highest yield of the highest purity product in the most efficient manner. One would have had a reasonable expectation for success because such modifications are routinely determined and optimized in the art through routine experimentation.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1 and 3, 5, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable Winge (US 6,399,357) in view of Chang (US 5,250,662), http://www.asahi-kasei.co.jp/planova/en/product/filters.html (accessed online 6/4/08) and Burnouf (Virol. Safety Aspects of Plasma Derivatives, 1993, cited in the IDS of 01/06).

Winge and Chang are relied upon as above. Winge also teaches that the degree of fineness of the filters is normally given as pore size or the approximate molecular weight at which the molecules are stopped by the filter. Winge goes on to teach Planova filters Planova 15 and Planova 35 which are used for smaller viruses (column 5, lines 50-54).

http://www.asahi-kasei.co.jp/planova/en/product/filters.html teaches that Planova filters are available in single-use, self-contained modules in mean pore sizes of 15 nm and 35 nm as in the instant limitations of claims 3, 5 and 7 [column 5, lines 50-54].

Winge teaches that the method reduces the residence time and the extent to which the solution needs to be diluted and optimizes the yield when virus-filtering primarily proteins (e.g., column 1, lines 15-23).

Burnouf et al. teach viruses of various sizes and shapes [pages 201-203], including the smallest parvoviridae virus being 18-26 nm in diameter (as in instant claim 3: "pore size 10-20 nm") and the largest poxviridae 300-45 x 170x260 nm in size (as in instant claims 5 and 7: "pore size 35-200 nm) in plasma derivatives.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Winge and Chang by having a pore size of 10-20 nm (see column 5, lines 50-54 of Winge) or prefilter at a pore size of 35-200 nm (e.g., Winge, column 5, lines 50-54). The skilled artisan would have been motivated to do so in order to purify the albumin with a smaller time of residence and optimized yield as taught by Winge (column 1, lines 15-23) for purification from viruses such asparvoviridae which is 18-26 nm in diameter (Burnouf, pages 201-203; Winge, column 5, lines 50-54). There would have been a reasonable expectation of success, because Winge teaches 15 nm pore size filters Planova 15 and 35 nm Planova 35 (http://www.asahi-kasei.co.jp/planova/en/product/filters.html) and because filtration of larger viruses such as poxviridae (300-45 x 170x260 nm in size) was also known in the art (Burnouf, pages 201-203, Winge column 5, lines 50-54) and because Winge, Chang, and Burnouf teach purification of albumin/plasma derivatives for therapeutic applications. The adjustment of particular conventional working conditions (e.g., determining appropriate purification steps including prefiltration from within those taught

by the prior art, determining appropriate order of the steps and/or selecting appropriate size pores for filtration within such method) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. As such, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g., filtration pore size, purification steps, and order thereof), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.". *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2145.05). One would have been motivated to determine all optimum and operable conditions in order to achieve the highest yield of the highest purity product in the most efficient manner. One would have had a reasonable expectation for success because such modifications are routinely determined and optimized in the art through routine experimentation.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marcela M Cordero Garcia/
Examiner, Art Unit 1654

06/08 MMCG